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AdvaMed
Advanced Medical Technology Association

December 6, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852

Re: Docket No. 00D-1539. Draft Guidance for Industry; Electronic Records; Electronic Signatures, Maintenance of Electronic Records

Dear Sir or Madam:

I am writing on behalf of the AdvaMed Part 11 Issue Working Group, which represents a cross-section of our member companies affected by the rule. AdvaMed, the Advanced Medical Technology Association, (formerly the Health Industry Manufacturers Association) represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of $159 billion purchased around the world annually.

We have reviewed the subject document in detail and have developed a number of comments, both general and specific. The general comments are addressed below, and the specific comments are contained in the attached table.

General Comments

We believe that this guidance is inappropriate and should be withdrawn. The fundamental precept in the document is that the "processability" of electronic records must be maintained. The language of the regulation does not address the concept of processability, and guidance is not the proper venue for introducing new regulatory concepts. This would be handled correctly through the formal rule making process, and we object strongly to this attempt to extend the regulation without formal notice and comment rulemaking.

It appears that FDA has once again in the development of Part 11 guidance lost sight of the purpose and limitations of this rule. As we understand it, Part 11 is intended to supplement and complement the predicate rules that actually set the standards for record keeping. Part 11 guidance should not be adding to the record keeping burden; it should be clarifying it. It is

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hard to understand why FDA should need to be able to "process" old records. It should be adequate to have sufficient information archived to reconstruct the values in the records, much as is the case now with paper records. This is particularly important when one compares the cost of the schemes proposed in the guidance against the frequency with which records are or would be "processed." We believe that it would be hard to create a global cost-benefit scenario that would make sense.

Finally, we would do not understand how the reprocessability recommendation supports the goal of patient safety, which we believe, is the primary justification for and purpose of medical devices regulation.

We hope that our comments prove useful. Please contact me (202.434.7230, *bliebler@AdvaMed.org*) with any questions regarding these comments.

Sincerely,

Bernie Liebler
Director
Technology and Regulatory Affairs